

1 UNITED STATES DISTRICT COURT  
2 SOUTHERN DISTRICT OF FLORIDA  
3 WEST PALM BEACH DIVISION

4 CASE NO. 20-md-02924-ROSENBERG

5 **IN RE: ZANTAC (RANITIDINE)** .  
6 **PRODUCTS LIABILITY** . West Palm Beach, FL  
7 **LITIGATION.** . April 30, 2021  
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10 STATUS CONFERENCE (through Zoom)  
11 BEFORE THE HONORABLE BRUCE REINHART  
12 UNITED STATES MAGISTRATE JUDGE

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1           *THE COURT:* All right. Good afternoon, everyone.  
2 This is Case Number 20-2924, In Re: Zantac (Ranitidine)  
3 Product Liability Litigation. We are here for a status  
4 conference as a followup to some matters that we discussed last  
5 Friday.

6           Let me begin by recognizing counsel for the Plaintiffs  
7 who will be appearing this afternoon.

8           *MS. FINKEN:* Tracy Finken on behalf of Plaintiffs.

9           *MS. LUHANA:* Roopal Luhana for the Plaintiffs.

10          *THE COURT:* Good afternoon to both of you. On behalf  
11 of Defendant GSK.

12          *MR. SACHSE:* Will Sachse on behalf of GSK.

13          *THE COURT:* Thank you. On behalf of Boehringer  
14 Ingelheim.

15          *MR. SHORTNACY:* Michael Shortnacy of King & Spalding  
16 on behalf of BI. Good afternoon.

17          *THE COURT:* Good afternoon to all of you. Today is a  
18 followup to the hearing we had last week. I know I set a  
19 couple of deadlines. I had one soft deadline, a couple of hard  
20 deadlines, some intermediate deadlines, and then in the  
21 meantime, I got a motion this morning relating to some  
22 additional time relating to what I believe are the batch  
23 records. I wanted to talk to you about that. My inclination  
24 is to grant the motion, but I did want to talk to you about it.

25          If we are going to do that, I want to make sure we

1 give you enough time. I think these repetitive, give us a few  
2 more days, isn't really as helpful as maybe giving you a hard  
3 deadline, but give you enough time for the hard deadline.

4 So, let me turn to Ms. Finken. What do you think is  
5 the logical order to address the issues? You know what has  
6 happened in the meantime, so you tell me what you think is the  
7 right order.

8 *MS. FINKEN:* Well, I think it probably will be a quick  
9 discussion on the update on GSK as far as I am concerned. We  
10 only have limited information that has been provided so far. I  
11 think Mr. Sachse can probably give you some additional  
12 information on where they stand with what they have been doing,  
13 and then Ms. Luhana can address the batch records discussion.

14 *THE COURT:* Great. Let me circle back a second. My  
15 recollection and my review of the transcript is, I think there  
16 were four specific deadlines that I had set. One was the batch  
17 records, which we will take last. One was, I directed GSK to  
18 provide to the Plaintiffs the fields that might exist in the  
19 PIER database by two days ago, and that by today to provide  
20 them with the data that fits into those data fields.

21 And then last, I set a soft deadline for a week from  
22 Wednesday, and to be candid, I can't remember what it was a  
23 soft deadline for. I think it was having to do with the delta,  
24 we talked about the difference between what was listed in  
25 Exhibit C and what was listed in Exhibit B.

1           Mr. Sachse, maybe you can clarify that for me.

2           MR. SACHSE: Sure, your Honor, and maybe I will take  
3 them in order.

4           So, first, on the PIER reports, the fields, we did  
5 provide those fields to the Plaintiffs earlier this week, and  
6 it actually turns out that they had those fields in the  
7 production already, but we got confirmation that they do, in  
8 fact, have all the fields.

9           We are now in the process, and I expect it is going to  
10 come out today, I was actually hoping it would be out by now, a  
11 revised PIER report with all of those fields with the data in  
12 those fields to the extent there are data in the fields. In  
13 essence, they are going to have to take a look at that and then  
14 the ball will be back in their court.

15           They can come back to us and we will be happy to meet  
16 and confer and talk about whatever other information they want  
17 to talk about with respect to that.

18           Sort of similar situation with what I call the PIER  
19 additional studies report. So, just to kind of orient, we have  
20 gotten a series of essentially Excel spreadsheets from Ms.  
21 Finken identifying studies or entries in the PIER reports that  
22 are of interest to them, so we went back and the first step  
23 was, let's see what is in the production already. We  
24 identified that and shared that with them last week.

25           We also identified of the remaining, the delta as it

1 were, which I think is something like 190 additional studies  
2 that they had identified that are not in the productions. We  
3 identified, I think, 20 of those, 21 of those, that we said we  
4 are going to go take a look at them. We identified a handful,  
5 maybe 14, 15, that we said we are struggling to see why we  
6 should bother, and for the vast majority we marked them as  
7 let's talk. Again, we just have to set that up probably for  
8 next week and have that discussion.

9 It probably would be helpful to have more  
10 scientifically inclined folks involved in that discussion as  
11 well because for some of this it really is going to be talking  
12 about the type of study, the type of information that might  
13 appear on that.

14 That is where we are on that assignment.

15 Related is Medtrack. You might remember, this is that  
16 sheet that I think we sort of tussled a little bit about what  
17 is it and what isn't it. Bottom line is, it's 762 studies  
18 identified on the sheet. We went and again, with the Court's  
19 direction, we provided the Plaintiffs kind of a status report  
20 of which of those studies appear in the production already and  
21 which do not, and I think the breakdown, as we reported last  
22 week, was that there are 500 and -- let me do it this way.

23 There are 227 that have been produced out of the 762,  
24 so that leaves 535. They fall into a number of different  
25 categories, and this is really the homework that we have been

1 doing this week. The team has been looking through GSK's files  
2 to identify additional studies that appear on that Medtrack  
3 sheet. We have found what I would say 40 entries that are very  
4 promising. We think we are likely -- we are going to pull  
5 them, we are going to look at them, and obviously, if they are  
6 responsive, even if it turns out not to be the actual study on  
7 the sheet, we will be producing that. That is in process now.

8 And actually, I did get -- in the nature of breaking  
9 news, just a few minutes before this hearing, I think we found  
10 an additional 12, so the total number is 52 entries on that  
11 sheet that we think are good candidates for being responsive  
12 and/or being the studies that are identified. All of that  
13 said, our investigation is continuing.

14 The challenge is it would be -- in a perfect world  
15 everybody would follow naming conventions, so when you have a  
16 study listed on Medtrack and you have a study listed on PIER  
17 they use the exact same title. Unfortunately, that didn't  
18 happen all the time. Unfortunately, the sort of study ID  
19 number didn't always follow from one to the other.

20 So, we are doing what I would call fuzzier searches to  
21 see if we can identify additional entries that are reasonably  
22 likely to contain the studies that we haven't yet been able to  
23 locate.

24 At the same time, because my poor colleague, young  
25 Noah Becker, last week probably stayed up for two days straight

1 to look through our productions to find the studies from  
2 Medtrack, we are doing a closer inspection of the materials  
3 produced to date just to see if we missed any. Just as last  
4 week, we are happy to continue updating the Court and updating  
5 the Plaintiffs on our progress.

6 I think that that is where we are on Medtrack.

7 And then the last bit of homework was, if you recall,  
8 we had the discussion about the custodial -- the potential  
9 custodians and the HR information.

10 *THE COURT:* Yes, yes.

11 *MR. SACHSE:* Last week we provided the Plaintiffs with  
12 what we had at the time, which was titles for these folks, and  
13 if they were active employees or if they had left, when they  
14 left. We went back this week and we found -- where available,  
15 we found start dates for these people as well. I know that the  
16 Plaintiffs haven't had a chance to look at that because I sent  
17 it literally 20 minutes ago over to the other side.

18 So, that is where we are.

19 *THE COURT:* Thank you, that is very helpful. Let me  
20 turn to the Plaintiffs in a second.

21 Before I do that, and I think I said this last time,  
22 but just in case, let me make it clear again. All we are  
23 trying to make sure we have here is an open and clear dialogue  
24 between the two of you. You are allowed to disagree.

25 It seems to me there are a couple of responses.



1 Plaintiffs have made a request for production and GSK can  
2 either say, look, it exists and we are going to give to it you,  
3 and we will tell you where we are in that process, but you are  
4 going to get it and here is where we are. We now have that  
5 process in place, it seems like that dialogue seems to be  
6 ongoing pretty well from what I am hearing.

7 Another alternative is, we looked and it doesn't  
8 exist, conversation comes to an end. We looked, it doesn't  
9 exist. One response might be, look, we have conducted a  
10 sufficiently reasonable search under the circumstances, we are  
11 not going to look anymore, we don't have to; or we found it,  
12 but we are not going to give it to you, we have an objection.

13 Any of those are perfectly acceptable truthful  
14 answers. The Court has no view as to whether that is a right  
15 answer or a wrong answer. They are perfectly appropriate  
16 answers.

17 What I want to be sure we are getting at, and this is  
18 what I want to hear from the Plaintiffs on specifically is, if  
19 one of the answers is, look, either we are not going to look  
20 any more or we are not going to give it to you, then you are  
21 going to have to bring that before the Court and we're going to  
22 have to litigate it, you're going to have to file a Motion to  
23 Compel, and that is perfectly fine. I will litigate that when  
24 the time comes.

25 I just want to make sure, before we get to that point,

1 that we have transparency and we're all pointing at the same  
2 bull's eye, I guess is the answer.

3 So, with that kind of lead-in, let me turn to Ms.  
4 Finken or Ms. Luhana and you can respond to what I said, you  
5 can respond to what Mr. Sachse said, or you can raise any new  
6 issues you want to raise.

7 *MS. FINKEN:* Thank you, your Honor. Tracy Finken on  
8 behalf of Plaintiffs.

9 I will just go in the same order that Mr. Sachse went  
10 in in terms of the different spreadsheets that we discussed at  
11 the last hearing.

12 Mr. Sachse did provide us with the fields, as they  
13 were required to do on Tuesday, and they identified a very  
14 small spreadsheet that was in the prior production, I think  
15 there were maybe 12 entries on it that had those fields  
16 already. We have looked at the fields.

17 We believe that once we receive the full spreadsheet  
18 with the data in the fields that will help us narrow our focus  
19 on this PIER request and where we are at. We are hopeful of  
20 that based upon what these fields look like on their face. We  
21 will see if it is actually populated with data once we get it.

22 That is due to us today, so once we receive that, we  
23 will look over that and discuss that with Mr. Sachse, and I  
24 think the Court had directed us to file a Motion to Compel if  
25 there was going to be a dispute over any of the productions

1 from PIER.

2           Once that takes place, what we will need to figure out  
3 is timing of any production ordered by the Court because, as  
4 your Honor is aware, we are supposed to be filing a motion in  
5 relation to the PTO 30 deadlines next Friday, and depending on  
6 what is in this PIER production and the timing of that, that  
7 may impact any potential schedule that we would request under  
8 that motion.

9           So, I just wanted to put that on your Honor's radar so  
10 that you are aware of that. So, that is one in terms of the  
11 PIER database.

12           As far as the Medtrack spreadsheet goes, Mr. Sachse  
13 did provide us with that information last week. Hopefully we  
14 will get an updated spreadsheet relatively soon. I know that  
15 the deadline that you set for next week is related to the  
16 Medtrack spreadsheet, I believe, and I believe the order was  
17 that by next Wednesday, the 5th, we are to be provided with the  
18 results of the search for those studies, whether or not they  
19 are going to produce them, and whether or not they are going to  
20 object to producing them.

21           Hopefully we will be in a better position next week to  
22 see where we are on those 500 and some missing human clinical  
23 trials from the Medtrack spreadsheet.

24           I think that is where we are as far as those two  
25 items.

1           In terms of the custodial file request, Mr. Sachse is  
2 correct, he sent us a spreadsheet with additional information.  
3 I have not had a chance to look at it, I am taking his  
4 representation as true that that is what it contains. We will  
5 take a look at that and start those discussions next week in  
6 terms of the tranche 2-B custodial files.

7           *THE COURT:* Wonderful.

8           *MS. FINKEN:* Hopefully we are on the right path in  
9 terms of getting the information that we need to determine  
10 whether there is a dispute or not a dispute. And then the next  
11 question is really going to be in the timing on production so  
12 we can address that in the overall PTO 30 schedule and that  
13 briefing.

14           *THE COURT:* That is very helpful. Let me ask you  
15 straight out, Ms. Finken. You have expressed over a number of  
16 months that the major concern is -- you kept saying a lack of  
17 clarity, you just weren't sure. Do you feel that we have now  
18 addressed that issue in a way that is allowing the case to move  
19 forward meaningfully?

20           *MS. FINKEN:* Yes, your Honor, I do think that this  
21 will be very helpful for us to determine whether or not we  
22 actually have a dispute so that we can tee it up and get  
23 finality on what to expect and when, and that is going to give  
24 us a lot of clarity and insight on what we need to request in  
25 terms of the PTO 30 deadlines and where we go from here with

1 those.

2           *THE COURT:* Very well. Judge Rosenberg is managing  
3 that part of the process, so I will stay out of PTO 30. I'm  
4 glad to hear the rest of this seems to be, from your  
5 perspective, moving in the right direction.

6           Just so the record is clear, I didn't direct the  
7 Plaintiffs that they had to file a Motion to Compel. I said,  
8 it just seems if we are going to have a dispute, to file a  
9 Motion to Compel sooner rather than later. Clearly, if you  
10 don't have to file one and you can work this out, that is  
11 always the best world, but I am happy to rule if I need to.

12           If there is nothing else that I am hearing from either  
13 side at least on those topics, or anything else currently  
14 relating to the GSK production, other than the batch records  
15 that we are going to talk about in a second, you don't need any  
16 further orders from the Court. Ms. Finken, you don't need any  
17 further involvement from the Court on those issues right now?

18           *MS. FINKEN:* I don't believe so, your Honor. The  
19 question is really going to come down to if these  
20 Medtrack studies are found and identified, the timing for  
21 production because, as your Honor is aware, there is a May 14th  
22 deadline for production of clinical and preclinical trials and  
23 I don't know what Mr. Sachse's intent is in terms of producing  
24 what they find from that Medtrack spreadsheet that would  
25 classify as a clinical trial. Obviously that all has an

1 impact.

2           *THE COURT:* One step at a time. Let's figure out what  
3 is there, then they can decide whether they are going to object  
4 or not object. Then, if you really want to have a nice fight,  
5 you all can fight about whether they have substantially  
6 produced everything they need to produce by May 14th, or  
7 whether they have not substantially produced.

8           I hope we never have to resolve that question as to  
9 what the term "substantial production" actually means. I am  
10 not quite sure how to do that, but I am sure we will figure it  
11 out if we have to.

12           Thank you both very much. Let me turn to Ms. Luhana  
13 on the batch record issue.

14           *MS. LUHANA:* Sure, Judge, Roopal Luhana for the  
15 Plaintiffs.

16           Judge, we filed a motion to extend the time to come to  
17 a proposal for batch records, as well as stability testing  
18 results and records. We have done that because we need more  
19 time to continue the conversation.

20           This is an iterative process. As you are aware, the  
21 product has been on -- was on the market for almost 40 years,  
22 and so we are trying to focus our discovery on what we need and  
23 tailor the discovery accordingly.

24           In order to do that we need to know what BI and GSK  
25 did on the front end, like what type of testing they did, what

1 the testing parameters were, what kind of processes they had in  
2 place and how that was set up.

3           Once we know that, once we know the testing and the  
4 investigation that was being done and the tools they were using  
5 for the testing, what they had in place, we will be able to ask  
6 for specific testing results, chromatograms, and lab tests.  
7 That is why we need more time to continue the dialogue.

8           *THE COURT:* Back to the same question I asked Ms.  
9 Finken, do you feel there is a productive and transparent  
10 dialogue where they are telling you, look, this is what we did,  
11 we are reserving the right to object to having to give you the  
12 records, but we will tell you how the process worked?

13           *MS. LUHANA:* It is taking time to get there, Judge,  
14 because the Defendants will say that they produced certain  
15 SOPs. When they identify those SOPs for us, we look into those  
16 SOPs, they don't have the answers we are looking for. For  
17 example, an SOP on stability testing, if a product failed  
18 stability testing, then what kind of investigation is being  
19 done? What type of testing is being done?

20           We don't have those answers and that is why the  
21 dialogue has to continue and that is what we are doing  
22 currently. We are asking for certain protocols and procedures  
23 in place. Once we get those protocols and procedures -- as you  
24 can appreciate, this is a long time span, the testing changed  
25 over time, so we are looking for those processes.

1           Once we get those answers, and we review those  
2 protocols, then we can tailor our discovery as to exactly what  
3 we need, and we may say, hey, we don't need the testing that  
4 you did from 1980 to 1990, but we need this testing based on  
5 the tests that you were using at the time.

6           *THE COURT:* Understood. I hear you loud and clear.  
7 Let me turn to Mr. Shortnacy on behalf of BI.

8           *MR. SHORTNACY:* Your Honor, thank you, it's Michael  
9 Shortnacy. I would just like to pick up on a couple of words  
10 from Ms. Luhana's statement.

11           Narrowly tailored and focused requests, those are  
12 obviously things that BI is keenly interested in. I received,  
13 prior to this conference, a detailed communication from  
14 Plaintiffs outlining some of these questions, and what BI's  
15 concern is that we do need to keep the conversation focused.  
16 Special Master Dodge is working very hard with the parties to  
17 do that.

18           With respect to the question of batch records  
19 themselves, as your Honor will recall, BI started scanning and  
20 producing the hard copy records, the first production was on  
21 April 2nd. We had a meet and confer with Plaintiffs where we  
22 walked through the contents of -- you will remember there is a  
23 bag, envelopes within the bag, and the aluminum foil. I think  
24 you remember talking about that.

25           We walked the Plaintiffs through that, where to find



1 the test results that are in the loose papers at the end of the  
2 bag, and today -- as of today, BI will have produced 986  
3 complete bags of records, that is 40,000 scanned documents.  
4 So, BI is moving swiftly and at great cost to provide what  
5 Plaintiffs have asked for by way of the batch records.

6 What we are concerned about is making sure that the  
7 conversation stays focused, that the information the Plaintiffs  
8 seek is obtainable and achievable for us to actually provide,  
9 and as I said, I believe Special Master Dodge's assistance has  
10 been instrumental in this, pushing this forward, but that is  
11 very much where we would like to stay, in this zone of narrowly  
12 tailored.

13 *THE COURT:* Okay. I appreciate that. I will say sort  
14 of the same thing I said on the flip side, which is, it is  
15 perfectly appropriate at some point, if BI's position becomes  
16 we are not required to look any more, we have given you a lot,  
17 we have been responsive, we have negotiated, but at some point  
18 we are not required to look at every piece of paper that ever  
19 was generated in the history of the company, you have the right  
20 to do that.

21 The point is, if you reach that point, please tell the  
22 other side that is the point you have reached so they can then  
23 act accordingly and file whatever motions they feel they need  
24 to file.

25 What I am hearing from both sides is that there is a

1 productive dialogue going on, that neither side has reached  
2 that point yet where BI is prepared to dig its heels in or that  
3 the Plaintiffs feel that they are being completely stonewalled,  
4 that there is a productive dialogue working with the special  
5 master, and so I will grant the additional time.

6 Ms. Luhana, I am looking at the motion now, you wanted  
7 until the 14th, so it is an additional two weeks; is that  
8 correct?

9 MS. LUHANA: Yes, your Honor.

10 THE COURT: Okay. Mr. Shortnacy, any objection to the  
11 two weeks?

12 MR. SHORTNACY: No, your Honor, that would be  
13 acceptable for BI.

14 MS. LUHANA: Your Honor, just one thing to note, in  
15 terms of it being an iterative process, BI had produced the  
16 batch records early April, and they were largely in Spanish.  
17 So, before we come to a conclusion on exactly what we need and  
18 asking them for further production of batch records, we need to  
19 review them. That is why these things take time, and during  
20 the meet and confer process actually was the first time we  
21 learned that some of these batch records -- part of the batch  
22 records and the lab results are electronic in a database.

23 Hopefully we can circumvent the process of producing  
24 paper batch records because now that we have learned electronic  
25 system in place, a database in place, we can hone in on what is

1 in that database and hopefully BI will be able to produce that,  
2 but, as I said, the conversation is ongoing.

3 *THE COURT:* That's fine. As long as you are having a  
4 productive dialogue, and it is not taking unduly long, which I  
5 don't think it is at this point, I am perfectly happy to give  
6 you the time that you have asked for.

7 Mr. Sachse, I do note that the motion was filed on  
8 behalf of both BI and GSK, although I don't see your  
9 signature -- there it is, you are on a different page. I  
10 apologize. I assume you have no objection.

11 Do you want to just adopt what Mr. Shortnacy said or  
12 do you have anything you wanted to add?

13 *MR. SACHSE:* I have no objection, of course. I  
14 briefly want to say, I am not going to quibble with Ms. Luhana  
15 over how much information they have or what they are looking  
16 for. I think that might be for another day. I will just note  
17 I think we had a good meeting earlier this week, provided some  
18 information, agreed, they had identified a few things that they  
19 wanted us to look for and we are agreeing to do that. Most  
20 notably a couple of things.

21 One, we found a number -- a very large number of  
22 historic paper batch record documents in Singapore, and we have  
23 now pulled a sample. It is a lot, but we have pulled a sample,  
24 and we are going to be getting that sample over to Ms. Luhana  
25 and to the Plaintiffs early next week or sometime next week.

1           The other thing, you might recall that last week we  
2       had some discussion about the pictures, the chromatograms that  
3       were housed in a database that we can't access easily, we can't  
4       search it easily.

5           We think we have come up with a -- it is not an  
6       elegant solution, but it is at least perhaps a solution that  
7       will give us better insight into how easy this is going to be,  
8       and the simple explanation is, we are letting the search run  
9       for about a week, and we think that at the end of the week,  
10      when the right people who know what to look for come back and  
11      are in the office, or the virtual office, they will be able to  
12      get us a better sense of can we find these 16 records or not  
13      and how easy it is.

14          Obviously, we will share that information with  
15      Ms. Luhana and Ms. Finken.

16          *THE COURT:* Very well. Help me out, which PTO was it  
17      where we originally set the deadline? PTO 63 had the original  
18      deadline of April 16th, which was then extended?

19          *MS. LUHANA:* Correct, your Honor, it is PTO 63.

20          *THE COURT:* I am going to have to do an order when  
21      this hearing is over, so I want to make sure the record is  
22      clear. To the extent the parties are requesting a two-week  
23      extension on the deadline that was set in PTO 63, I will grant  
24      that extension until May the 14th. I have granted that motion  
25      at Docket Entry 3352.

1           Mr. Sachse, in looking at my notes, I did notice --  
2           and we talked about this -- when I said I was going to set a  
3           deadline of next Wednesday for you to produce the Medtrack  
4           materials, I told you it would be a soft deadline, and if you  
5           had some issues you wanted to raise today if you didn't think  
6           you could meet that deadline, I would hear you.

7           If you want to wait and if it turns out on Monday you  
8           realize you have an issue, you can always file something, but  
9           if we're all together today and there is an issue, I'd just as  
10          soon hear it if you know.

11          MR. SACHSE: Thanks for the opportunity. I think that  
12          makes sense to just return to Medtrack for a moment, for a few  
13          issues or a few reasons.

14          One is, as I mentioned, our investigation is  
15          continuing, and do I think that we will one hundred percent  
16          definitively know by next Wednesday what we have and what we  
17          may still be able to find? I think that it is unlikely. I  
18          think this is going to be an iterative process and we will, of  
19          course, continue to talk to the other side about that.

20          I also note, I think that the order speaks to giving  
21          the Plaintiffs more clarity about whether we are going to be  
22          objecting to the production of studies if we find them.

23          I spoke with Ms. Finken last week, or maybe it was an  
24          email, but explained that our position is, we are looking for  
25          these studies, if we find them and they are responsive, we are

1 producing them. We do not have a legal objection to doing  
2 that.

3 Now, at some point and you raised -- you touched on  
4 this earlier, we might reach a point where we say we have now  
5 done reasonable searches, we have exhausted the reasonable  
6 places we can look, and if you want us to continue looking,  
7 then maybe we need to tee up a motion, or they need to tee up a  
8 motion. I would suggest that we are not there yet. I think  
9 there is more work for us to be done. I understand the  
10 Plaintiffs want to know what does the timeline look like, when  
11 are we going to get these.

12 Just on that point, I will say it is a rolling  
13 production, as we have been doing for the last several months.  
14 I believe this week our productions included 14 of the studies  
15 that we have found, 14 additional studies that we found from  
16 this Medtrack sheet, and we will continue to do that on a  
17 rolling basis.

18 I do want to touch on that May 14th deadline, because  
19 I think that there is maybe some lack of consensus about what  
20 that means, and I will take you back to when we were first  
21 talking about the May 14th deadline, or extending the deadline.

22 We, in our papers, fairly consistently made it clear  
23 that when we are talking about May 14th and substantial  
24 compliance or substantial completion, that we were really  
25 focused on the studies, the 2300 entries that we had identified

1 that we were going to look at and we were going to produce if  
2 they were responsive. We are on track to do that.

3 I think there are a couple -- apparently there are a  
4 few very oversized documents that are taking a bit longer to  
5 scan and get through, but other than that, it looks like we are  
6 on track.

7 These additional requests, whether it is coming from  
8 PIER, whether it is coming through Medtrack, these are  
9 conversations that we wanted to have with the Plaintiffs. In  
10 February we started those conversations and I think the  
11 spreadsheets we are talking about now are a product of the work  
12 that they have done on their side and we have done in response.

13 That, to me, is -- I think of it as the followup  
14 discovery that is normal when you are talking about we have  
15 produced now millions of pages of documents, we have produced  
16 thousands of documents relating to studies, and we are talking  
17 about what we see as a smaller universe and we are whittling  
18 down that universe fairly quickly.

19 I think if you were to say, well, the expectation  
20 is -- or if the Plaintiffs were to say the expectation is you  
21 have to give us every study from that Medtrack list by May 14,  
22 I don't think that that is going to be possible. I want to  
23 make sure everybody understands that that is our position.

24 *THE COURT:* Again, I won't delve into that until  
25 someone formally brings it before me other than to say this.

1           The order speaks in terms of substantial production of  
2 noncustodial files. We can have a hearing -- I'm half joking,  
3 but not really. If we need to have a hearing to determine what  
4 that means, I guess we will figure out what that means when the  
5 time comes.

6           Let's talk about the real world that we are all living  
7 in, okay. Obviously all these new moving parts are connected  
8 because the Plaintiffs want to ask and the Defendants want to  
9 ask the Court to reconsider PTO 30. Well, you can't have an  
10 intelligent request until you know what you are going to get,  
11 and you can't really have an intelligent request about what you  
12 are going to get until you know what you have gotten.

13           I see that all these pieces fit together, and I can  
14 understand the Plaintiffs don't want to make a preemptive  
15 request for a PTO 30 modification and then find out later that  
16 there are 3,000 more studies that they are suddenly going to  
17 get and now their newly requested PTO 30 deadlines aren't  
18 workable deadlines. I hear that.

19           I also hear on the flip side -- and this is why I  
20 think throughout this litigation Judge Rosenberg and I  
21 have always spoken in terms of substantial production because,  
22 again, we are living in the real world. There is so much  
23 discovery in this case, things may pop up at the last  
24 minute and we didn't want anyone to be feeling in a gotcha  
25 position that we did the best we could, we acted in good faith,



1 we produced this and now, all of a sudden something pops up and  
2 we are being accused of all sorts of bad things.

3 I understand the dynamic on both sides. Other than to  
4 say keep talking to one another, I think the more transparency,  
5 the better. The Plaintiffs may not like the answer they get,  
6 the Defendants may not like the answer they get, but at least  
7 if you all give each other the answers and ask the right  
8 questions people can act accordingly.

9 If the Plaintiffs have to then file something under  
10 PTO 30 saying we now understand GSK may have 250 more studies  
11 that we didn't know about, and we are not going to get them for  
12 at least another month, that affects what we have to ask for in  
13 PTO 30. They may not like it, but it is what it is, and the  
14 Court will act accordingly based upon that request.

15 If they think they are entitled to some other remedy  
16 because suddenly there is a slew of stuff that comes in at the  
17 last minute they can ask for a remedy.

18 So, I hear you. Thank you for putting it on the  
19 record, maybe more for the Plaintiffs than for me, now they  
20 know that is your position and know where you are coming from.  
21 I am not going to opine as to whether that is consistent with  
22 or not consistent with the PTO until somebody formally makes a  
23 motion and asks me to do that.

24 I will encourage you to keep talking so that the  
25 Plaintiffs can make an informed and reasonable request under

1 PTO 30. That is what the Court has asked them to do, and I am  
2 not suggesting GSK is not acting in that regard, but I think it  
3 is very important that they have that information as soon as  
4 they can have it. I will leave it at that.

5 At least for the time being, you are not asking me,  
6 Mr. Sachse, to extend the soft deadline of next Wednesday; am I  
7 correct?

8 MR. SACHSE: No. I am happy to, obviously, speak with  
9 the Plaintiffs and maybe we should talk about what precisely is  
10 expected on that soft deadline. Is that something to your  
11 Honor or is that something to the Plaintiffs?

12 THE COURT: No, to the Plaintiffs. If you and the  
13 Plaintiffs are in conversation and there is consent from the  
14 Plaintiffs that everything is -- the idea, if you remember, was  
15 you do have until May 14th to produce whatever it is you have  
16 to produce by May 14th, and we all sort of agree that whatever  
17 it was I was giving you a soft deadline in sort of fit within  
18 that category.

19 Technically, you could stand on your ceremony and say,  
20 well, we don't have to produce until May 14th, but for purposes  
21 of case management and transparency and all the things we have  
22 been talking about, we kind of agreed that you would provide  
23 them interim information by next Wednesday.

24 I said it is a soft deadline, so talk amongst  
25 yourselves. That is where I leave it. If the Plaintiffs feel

1     there is a reasonable dialogue and they are getting the  
2     information they need to, again, make the informed requests of  
3     the Court they need to make, I don't need to hear from you by  
4     next Wednesday.

5             I just wanted to give them some comfort that you  
6     didn't have permission from the Court to wait until the 13th  
7     and then show up and give them all of this information on the  
8     13th. That's all.

9             MR. SACHSE: Understood. Thank you for that guidance,  
10    that's helpful. Obviously, I will certainly be talking to  
11    Ms. Luhana and Ms. Finken, I don't know, probably ten, 15 times  
12    next week. We have a lot to talk about.

13            THE COURT: I'm sure you always do. Mr. Shortnacy,  
14    anything further on behalf of BI?

15            MR. SHORTNACY: No, your Honor, thank you very much.

16            THE COURT: All right. So, I have one other -- two  
17    other topics I want to take up. Before I leave these behind,  
18    Ms. Luhana and Ms. Finken, have I at least now dealt with all  
19    the issues you think are leftover issues from last week related  
20    to GSK and the ongoing GSK production?

21            MS. FINKEN: I believe so, your Honor. Sorry,  
22    Ms. Stipes, this is Tracy Finken on behalf of Plaintiffs.

23            You hit the nail really on the head for us on the  
24    issues with the PTO 30 schedule request, and this is why last  
25    week we had filed a request for an extension to file that

1 motion until next week because we wanted to be able to wrap our  
2 heads around and arms around where we were in terms of the  
3 production.

4 Clearly 500 and some missing human clinical trials is  
5 not a small issue, it is a pretty significant issue, and that  
6 is going to have some bearing on the schedule and impact the  
7 schedule going forward.

8 To the extent that we can get as much clarity as we  
9 can, that will help us fashion our request in terms of the PTO  
10 30 schedule. I think that that would be really helpful.

11 The last thing that we want to do on the Plaintiffs'  
12 side is request an extension of the PTO 30 deadlines and then  
13 have to go back and say we need another extension. We want to  
14 do it once and get it right and move forward.

15 So, to the extent that the sooner we get information  
16 about those human clinical trials and whether or not we are  
17 going to get them and when, the better in our view. Thank you.

18 *THE COURT:* Yes, I appreciate that. I am not going to  
19 rule on the PTO 30 request, that is at a higher pay grade than  
20 mine. One thing you might consider, because I know you are  
21 anxious to get your motion filed, I know the Defendants are  
22 anxious to see your motion, I know the Court is anxious to get  
23 your motion, and I am highly confident that Judge Rosenberg is  
24 not going to rule on that on the papers without talking to the  
25 lawyers and having some additional feedback.

1           So, to the extent you maybe can perhaps file that  
2 motion and put a contingency in there that says, look, if we  
3 can get this stuff from them by this date then these are  
4 workable deadlines, however, if we are going to have to wait  
5 this long to get it, these are really the workable deadlines,  
6 and at least get that down on paper. That will put the markers  
7 in the ground for the other side. They can respond and the  
8 Court can at least start moving that process forward.

9           If you wait until you really know everything to file  
10 your motion, you are never going to file your motion, and then  
11 all the deadlines are going to run, and we are going to have  
12 chaos. Again, I am not ordering you to do that, I leave it to  
13 you to think about whether that is a way that makes sense from  
14 both sides.

15           Likewise from the Defense, if the Defense is -- you'll  
16 respond accordingly. That was that issue I wanted to address.

17           Two other issues. I will be getting an order out this  
18 afternoon, but I know the special master conferred with the  
19 parties. Judge Rosenberg referred to me the motions relating  
20 to PTO 54 and PTO 60.

21           I am going to set a hearing for next Thursday. I just  
22 want the parties to understand it is not my intention to rule  
23 on anything. I don't have the authority from Judge Rosenberg  
24 to rule on those requests. What Judge Rosenberg has asked me  
25 to do is to make a record for you. Let you come in, go through

1 the requests, have both sides explain to me why they are  
2 requesting or objecting to the request, why it is important, so  
3 that we have a full record, everybody gets a chance to be fully  
4 heard, and then she can review that record and either rule on  
5 the papers, or if she believes it is appropriate, to then have  
6 followup hearings, have either her or me do followup hearings.

7 I didn't want anyone to prepare for that hearing with  
8 the expectation that the Court is going to rule and you have to  
9 be ready to get a ruling from the Court. It really is just  
10 about we saw the request, I have read the requests, and I just  
11 want to -- just as I kind of made sure we fully understand  
12 where you are coming from today, we just want to make sure we  
13 fully understand where the parties are coming from.

14 So, if that helps both sides prepare for that hearing  
15 next Thursday, since we were together today, I wanted to share  
16 that information with you.

17 *MS. FINKEN:* Thank you.

18 *THE COURT:* My other related point is, I saw Mr.  
19 McGlamry was on here. Can I ask Mr. McGlamry to turn on his  
20 camera for one second?

21 *MS. FINKEN:* Your Honor, he was ill yesterday, so I'm  
22 not sure if he is still on. Maybe -- I wanted to let you know.

23 *THE COURT:* I see his name is there. You can let him  
24 know this, at the LDC lunch today we took a vote that we should  
25 enter an additional PTO which is going to require him and his

1 wife to provide babysitting services beginning next Tuesday and  
2 extending for the foreseeable future. So, if the parties want  
3 to meet and confer and submit a proposed PTO or present  
4 unilateral PTOs, either way.

5 In all seriousness, I just wanted to wish him  
6 congratulations, I understand he is about to become a  
7 grandfather again, and also reiterate to the parties here  
8 something that Judge Rosenberg and I said to the LDC people a  
9 few minutes ago.

10 This is a very important case for everybody involved,  
11 the parties, the lawyers, the Court, and everybody else, but  
12 life is more important. This case is going to go on for  
13 awhile, and people are going to have important life events with  
14 spouses, with significant others, with children, with parents,  
15 significant birthdays, and things of that nature. Please,  
16 please make time for that. It is really important that all of  
17 us are going to live together a long time on this case, and it  
18 is important that we really do make time, and proactively make  
19 time to be with our families, to be with our loved ones and  
20 have happy occasions.

21 I wanted to congratulate the McGlamry family, and  
22 anybody else who is having a significant event, please,  
23 congratulations and enjoy.

24 With that, let me turn back to the parties. Ms.  
25 Finken, anything else you wanted to take up this afternoon

1 while we're together?

2 MS. FINKEN: I don't think so, your honor, and thank  
3 you for that. I will make sure to pass that along to Mr.  
4 McGlamry. I am sure he will very much appreciate your well  
5 wishes. I know he is really looking forward to next week.  
6 Thank you.

7 THE COURT: That was also directed to you, too, spend  
8 some time with your children that doesn't involve them yelling  
9 in the background while you're trying to talk to Mr. Sachse.

10 MS. FINKEN: Yes, he's used to that. They know Mr.  
11 Sachse.

12 THE COURT: I should order you two to go to a  
13 Phillies' game together and work it all out.

14 Mr. Sachse, anything else you wanted to take up this  
15 afternoon on behalf of GSK?

16 MR. SACHSE: Nothing, your Honor, other than I would  
17 be happy to go to a Phillies' game with Ms. Finken.

18 THE COURT: Mr. Shortnacy, anything else on behalf of  
19 BI?

20 MR. SHORTNACY: Nothing, for us, your Honor, thank  
21 you.

22 THE COURT: Thank you, everybody. I will see some of  
23 you together next Thursday, and otherwise have a good weekend.  
24 We will be in recess.

25 MS. FINKEN: Thank you, your Honor.



1           MR. SACHSE: Thank you.

2           *(Thereupon, the hearing was concluded.)*

3                           \* \* \*

4           I certify that the foregoing is a correct transcript  
5 from the record of proceedings in the above matter.

6  
7           Date: May 1, 2021

8                           /s/ Pauline A. Stipes, Official Federal Reporter

9   Signature of Court Reporter

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Pauline A. Stipes, Official Federal Reporter



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